

## REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 12 and 14-31) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recalled that the present invention provides a surgical instrument for preparing implant beds in a person's lower jaw, along with a related method for producing the implant beds via a drilling element having a spinous shape and a handle affixed thereto. Because of the anatomy of the lower jaw of many patients, which might be particularly weakened due to atrophy or other ailments, prior art implementation methods often do not permit a stable anchoring of the necessary implant posts of sufficient length without the use of further measures.

To overcome the inherent limitations of prior art instruments and methods, the present invention, as broadly claimed, provides a surgical instrument and related method, which permits a very atraumatic invasive procedure, which readily allows for the quick and complete healing of the implementation point in otherwise healthy patients with a high rate of success.

More particularly, the invention, as recited by Applicant's claims, provides a surgical instrument for preparing implant beds in a lower jaw of a patient, which includes a drilling element having a spinous shape and a truncated cone having a closed, solid tip with an outer surface line that is smooth and encloses an angle of no more than several

degrees with an axis of the truncated cone. The surgical instrument further includes a handle at an angle to the axis of the truncated cone with the spinous shape of the drilling element enclosing an angle with the handle and with the drilling element and the handle being non-coaxially positioned relative to one another.

As explained in Applicant's *Specification* at Page 3, line 18 – Page 4, line 20, it is important that the spine encloses an angle with the handle and that the surgical instrument permits vertical access to the lower jaw of the patient for introducing the implant, even for the patient's back teeth. As such, the angled shape resulting from the drilling element and the handle being non-coaxially positioned relative to one another is essential. For preparing the implant bed, the proposed surgical instrument is introduced, in advance, with the top surface of the truncated cone being introduced first, into an opening in the patient's lower jaw produced as further described in Applicant's *Specification*. The surgical instrument used has a diameter of the top surface of the truncated cone which permits penetration through the enlarged borehole in the corticalis as far as the adjacent spongiosa.

With a further introduction of the surgical instrument, because of the closed, solid tip conical design of the drilling element, the bore is enlarged; the adjacent bone tissue being forced radially outwards. The construction of the truncated cone, with a low conical angle and its smooth circumferential surface, permits manual introduction of the surgical instrument without a great application of force. It is important that the handle of the surgical instrument is arranged at an angle to the axis of the truncated cone. In this

manner, during work with the surgical instrument, an optimum position of the hand enclosing the handle and of the bore element is ensured relative to the opening in the lower jaw. Further, by successive changes of the direction of the surgical instrument (*i.e.*, its penetration section or axial inclination), an enlargement, and also an uplifting, of loosened segments is achieved.

As will be explained in greater detail hereinafter, nowhere in the prior art is a surgical instrument for preparing implant beds in a lower jaw of a patient, which includes a drilling element having a spinous shape and with the spinous shape enclosing an angle with the handle for permitting a substantially atraumatic invasive procedure, and with the handle being non-coaxially positioned relative to the drilling element, either disclosed or suggested.

By the present amendments, Applicant has amended independent Claims 12 and 23 (and Claims 14-22 and 24-26 via dependency) to recite that the drilling element of the invention has a spinous shape and truncated cone that has --a closed, solid tip--. The shape of the truncated cone drilling instrument of the present invention, as now recited in Applicant's Claims 12 and 14-26, readily distinguishes the claimed invention over the prior art of Martin, U.S. Patent No. 4,330,278, which discloses a "truncated cone" with an aperture for placement of a drill file therein, as will be explained in greater detail hereinafter.

Applicant has also amended dependent Claim 26 to correct a typographical error to correct the wording of the claim to indicate that the recited angle at Claim 26, line 4, is

“70°.” Applicant thanks the Examiner for bringing the noted typographical error to Applicant’s attention.

Applicant has further amended dependent Claim 24 to remove the recitation of a means-plus-function element, which the Examiner had indicated rendered Claim 24 indefinite and thereby rejected Claim 24, pursuant to 35 U.S.C. §112, second paragraph. The Examiner had also similarly rejected dependent Claim 21, however, Claim 21 does not recite any means-plus-function element and therefore Applicant views the inclusion of Claim 21 as part of the indefiniteness rejection of the fourth Office Action to be in error. Alternatively, Applicant requests clarification of the 35 U.S.C. §112, second paragraph, indefiniteness rejection as it may apply to Claim 21.

In view of the foregoing, Applicant respectfully submits that the Examiner’s 35 U.S.C. §112, second paragraph, indefiniteness rejection of the fourth Office Action has been overcome and should now appropriately be withdrawn.

Applicant has also canceled dependent Claim 13, which recited the inclusion of “layered cones of a single drilling instrument,” which the Examiner indicated was not illustrated in the drawing figures of record and which formed the basis of the Examiner’s 37 C.F.R. §1.83(a) drawing objection of the fourth Office Action.

In light of the cancellation of dependent Claim 13, it is now submitted that the Examiner’s 37 C.F.R. §1.83(a) drawing objection is now moot.

Finally, Applicant has amended the Specification at Page 7, paragraph 3, to

correct a typographical error noted by the Examiner.

Turning now, in detail, to an analysis of the Examiner's prior art rejections of Applicant's claims, in the fourth Office Action the Examiner has rejected Claims 12-15 and 21-25 as being anticipated, pursuant to 35 U.S.C. §102(b), by Martin, U.S. Patent No. 4,330,278, on the contention that Martin discloses a surgical instrument for preparing implant beds in a patient that includes a drill element (10) having a spinous shape with a portion thereof that may be considered a truncated cone (34) that has a smooth outer line and which corresponds to an angle of no more than several degrees, along with a handle that has an angle with respect to an angle formed by an axis of the truncated cone, and wherein the drilling element and the handle are non-coaxially positioned relative to one another, thereby anticipating the subject matter recited in the enumerated claims of the anticipation rejection.

In reply to the Examiner's 35 U.S.C. §102(b) anticipation rejection of the fourth Office Action, a detailed analysis of Martin finds that the applied citation discloses an endodontic flow-through ultrasonic instrument holder device, which includes a "truncated cone," as designated by reference numeral 34, as explained by the Examiner. The truncated cone of Martin includes a central aperture (38) from which a drill file (22) extends.

In sharp contrast to that taught and suggested by Martin, the presently claimed invention, as set forth in amended independent Claims 12 and 23, recites a surgical instrument for preparing implant beds in a lower jaw of a patient which includes "a drilling element having a spinous shape and a truncated cone having a closed, solid tip

with an outer surface line that is smooth and encloses an angle of no more than several degrees with an axis of said truncated cone.” Martin discloses the inclusion of a truncated cone having a central aperture for retaining an instrument, while Applicant’s claimed invention has a truncated cone that is the drilling instrument and which is “closed” and has a “solid tip. In Martin, the useful instrument is not the “truncated cone” (34), but rather than drill file (22) extending therefrom.

In light of the foregoing, it is respectfully contended that the Examiner’s 35 U.S.C. §102(b) anticipation rejection of Claims 12-15 and 21-15 of the fourth Office Action has been overcome and should be appropriately withdrawn.

Separately, the Examiner has rejected independent Claim 23 as being obvious, pursuant to 35 U.S.C. §103(a), over Martin, taken in view of Nowak, U.S. Patent No. 5,997,298. It is the Examiner’s position that Martin discloses the claimed invention, as presented in the foregoing anticipation rejection. Nowak, as secondarily applied, teaches the use of multiple versions of the same instrument. The Examiner has therefore concluded that it would have been obvious to have constructed the assembly of Martin, taken in view of Nowak, to have included multiple versions of the same instrument with different diameters.

In reply to the Examiner’s 35 U.S.C. §103(a) obviousness rejection applying Martin, taken in view of Nowak, Applicant respectfully submits that the claimed kit of surgical instruments is comprised of individual instruments that vary from, and are patentably distinguishable over, the prior art of Martin for the reasons expressed above.



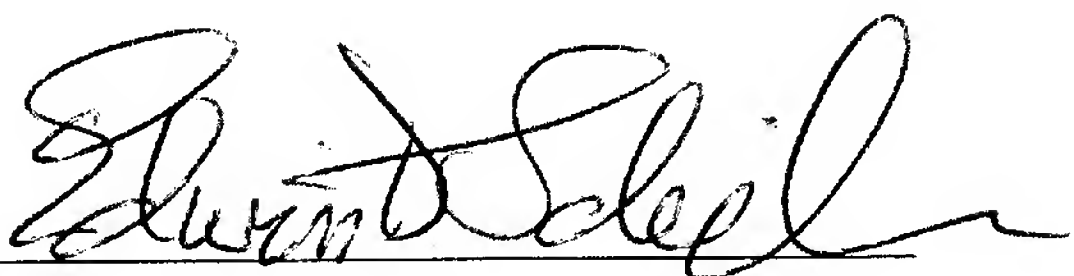
Applicant agrees with the Examiner's legal contention that the "mere duplication" of essential working parts is not a basis for patentability, however, the individual instruments themselves, as broadly claimed by Applicant, are patentably distinct over Martin, and the combination of Martin taken in view of Nowak by the application of similar reasoning, and consequently withdrawal of the Examiner's 35 U.S.C. §103(a) obviousness rejection of Claims 23-26 is respectfully requested. Stated differently, Applicant is not relying upon the "multiplicity" of instruments to support the patentability of Claims 23-26, but rather than patentability of the individual instruments themselves, notwithstanding multiple copies thereof for comprising the claimed surgical instruments.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 12 and 14-31) recite a novel and efficient surgical instrument for preparing implant beds in a lower jaw of a patient, which includes a drilling element having a spinous shape and with the spinous shape and truncated cone having a closed, solid tip with an outer surface line that is smooth and encloses an angle of no more than several degrees with an axis of the truncated cone, and enclosing an angle with the handle for permitting a substantially atraumatic invasive procedure, wherein the handle and the drilling element are not coaxially positioned relative to one another, which is patentably distinguishable over the prior art. According-

ly, withdrawal of the outstanding rejections and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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Enc.: 1. Petition for Three-Month Extension of Time for Response; and,  
2. EFT for \$555.00 (Three-Month Extension Fee).

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (*Account No. 19-0450*) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.